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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/073,881	05/06/1998	MAHENDRA S. RAO	T4903.CIP	1335

7590 07/08/2002

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/073,881

Applicant(s)

Rao et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 25, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 9-13, and 15-18 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9-13, and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 2/25/02 has been entered.
2. The objection to claims 2-5 under 37 CFR 1.75(c) is withdrawn due to the cancellation of these claims.
3. The rejection of claims 3-4 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of “mitogen” is withdrawn due to the cancellation of these claims.
4. The rejection of claims 1, 9-13 & 15 under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to recite sufficient “purification steps” for obtaining a “pure homogeneous population of mammalian/rat neuroepithelial stem cells” is withdrawn due the amendment of the claims. However, because a “pure homogeneous population of mammalian/rat neuroepithelial stem cells” is no longer required, re-instatement of the rejections under 35 USC 102(e) is necessitated, as indicated below.
5. Applicant's arguments filed 2/25/02 have been fully considered but they are not deemed to be persuasive.

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6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 9-13, 15 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of plating dissociated cells on a fibronectin substrate and a purification step on obtaining “pure, homogeneous populations of neuroepithelial cells”, etc., does not reasonably provide enablement for a method requiring “isolating a pure, homogeneous population of mammalian neural stem crest cells” by replating neuroepithelial cells onto laminin-coated or undefined substrates while removing FGF and/or chick embryo extract; especially when such methods alternatively result in a mixed population of more differentiated cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons made of record in Paper Nos. 13 & 19, and as follows.

Applicants argue on page 7 of the response that they “disagree with the Examiner’s suggestion that only three examples of dorsalizing agents are described in the specification”, and refer to pages 61-62 of the specification for “additional dorsalizing agents”. In contrast to Applicants’ assertions, page 7 and original claims 11-13 list only BMP-2, -4, & -7 as dorsalizing agents, in which no “dorsalizing agents” nor assays to discover/ “identify” “dorsalizing agents” are described on pages 61-62 of the specification, even though BMP-2, -4 & -7, etc. are mentioned as “promot[ing]/ regulating crest differentiation” which are different concepts and

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different in scope from the term, “dorsalizing agents”. In addition, note that no copies nor proper IDS has been filed for the references listed on pages 7-8 of the response, as it relates to the genus of “dorsalizing agents”; therefore, no proper consideration of this particular argument can be made. Therefore, Applicants’ arguments are not persuasive as it relates to claims 9 and 16.

Lastly, note that page 61 states that “BMP-2 appeared to be an antimitotic agent and significantly reduce the number of dividing cells present”; thereby, providing evidence that claims 9 and 16, as currently claimed, would not work (i.e., not “increase neural crest stem cell numbers”) without requiring undue experimentation to determine otherwise.

8. Claims 9 & 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the recitation “dorsalizing agent” remains ambiguous, in that the specification still lists only three examples of “dorsalizing agent”, as discussed in *pp* #7 above.

9. Claims 1, 9, 15 and new claims 16-18 are re-instated as being rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (U.S. Patent 5,589,376), and by Anderson et al. (U.S. Patent 5,824,489) because of the amendment of the claims to remove the recitation of “isolating a pure, homogenous population...”, as previously made of record in Paper No: 11.

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Note that the inclusion of EGF, bFGF and NGF (e.g., col. 12 of '376; col. 15 of '489 ) or the addition of forskolin (col. 16 of '376; col. 18 of '489) in the culture medium of the Anderson patents, met the limitations of "adding a dorsalizing agent" (i.e., as it relates to claims 1, 9, 15 & 16); absent evidence to the contrary. Note further that col. 8, line 66- col. 9 of '376 describes using fluorescence activated cell sorting (FACS) (i.e., antibody capture) using p75/LNGFR antibodies (i.e., as it relates to new claims 17-18), as does col. 10, line 34- col. 11, and col. 16, line 63- col. 17 of '489.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

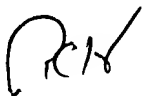
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

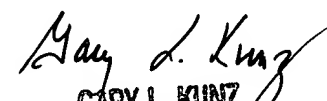
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
June 20, 2002



GARY L. KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600